

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/013,077 01/26/98 NAUSS

J

HM22/0224

EXAMINER

NASH & TITUS, LLC
3415 BROOKVILLE ROAD
SUITE 1000
BROOKVILLE MD 20833

WESSENDORF, T

ART UNIT	PAPER NUMBER
----------	--------------

1627

13

DATE MAILED:

02/24/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/013,077

Applic

Naus et al

Examiner

T. Wessendorf

Group Art Unit

1627

 Responsive to communication(s) filed on Nov 5, 1999 This action is **FINAL**. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

- Claim(s) 1-20 is/are pending in the application.
Of the above, claim(s) 1-14 is/are withdrawn from consideration.
 Claim(s) _____ is/are allowed.
 Claim(s) 15-20 is/are rejected.
 Claim(s) _____ is/are objected to.
 Claims _____ are subject to restriction or election requirement.

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
 The drawing(s) filed on _____ is/are objected to by the Examiner.
 The proposed drawing correction, filed on _____ is approved disapproved.
 The specification is objected to by the Examiner.
 The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 All Some* None of the CERTIFIED copies of the priority documents have been
 received.
 received in Application No. (Series Code/Serial Number) _____.
 received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- Notice of References Cited, PTO-892
 Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
 Interview Summary, PTO-413
 Notice of Draftsperson's Patent Drawing Review, PTO-948
 Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 1618

Applicants' election of Group III, claims 15-20 in Paper No. 10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-14 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Election was made **without** traverse in Paper No. 10.

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Inventor Scheherazade has not provided an oath or declaration.

The disclosure is objected to because of the following informalities: .

A). The status of all the continuing applications recited at page 1, lines 8-18 have not been provided.

B). Syntax and typographical errors too numerous to mention specifically. Examples of these errors are: "While **no** all peptid models" at page 4, lines 10-11; "..also **be** formation of several

Art Unit: 1618

hydrogen bonds.." at page 11, line 23. Typographical errors such as "reporesented" at page 4, line 23; "ration " at page 7, line 13 and the distances 15.0A, 11.0A and 14.0A at page 8, lines 13 and 15.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification fails to provide an adequate description of a vaccine comprising the minimized peptide. The specification provides at e.g., paragraph bridging pages 4 and 5 a mere generalized statement as to the minimized peptide that aid in vaccine design. Furthermore, the specification merely provides a technique for making a model that is structurally homologous to a receptor. Said receptor is then preliminarily screened for peptides for antigenic properties and its ability to elicit an

Application/Control Number: 09/013,077

Art Unit: 1618

immune responses. It is not apparent from the minimized peptide models whether said models have been predictive of vaccine effect since no vaccine has been made or tested to show the effect of the model as vaccine to the intended host. However, as a skilled would appreciate, the generation of an immune response, or neutralizing response in particular, cannot be equated with preparation of a protective vaccine. A vaccine is administered for the prevention, amelioration or treatment of infections disease. Thus, there is no indication that this model has been successfully employed as a vaccine.

Furthermore, there is no adequate description as to the synthetic peptides i.e., the kind and/or length or number of amino acid residues that modifies the "minimized" peptide to produce a synthetic peptide effective as a vaccine as recited. The following is a quotation of the second paragraph of 35

U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1618

A). Claim 15 is indefinite in its recitation of a "minimized" peptide and unclear within the claimed context, as to its metes and bounds. Furthermore, it is suggested to recite a vaccine composition, rather than vaccine alone. "Minimized" is misspelled. The claimed minimized and synthetic peptides, within the claimed context, appear to be the same especially since the specification does not provide any other residues that would modify the minimized peptides.

B). The use of a parenthesis (306-318) in a claim is improper as every feature or compound recited in a claim becomes a part of the overall subject matter. By placing terms in parenthesis renders the claim ambiguous as to whether or not it should be disregarded. It is suggested that applicants recite the region. The language "to form at least a portion" of a synthetic peptide is unclear since the preamble recites a synthetic peptide and not a fusion of synthetic and minimized(?) peptide.

Art Unit: 1618

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 15-18 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Reid (Jrnl. Of Immunology, April 15, 1993) .

The claimed vaccine comprising of a minimized peptide and a carrier is fully met by the composition of Reid which recites a minimized peptide that is used in the binding assay. It is considered that the composition of Reid would inherently or obviously be a vaccine since Reid discloses that the minimized peptide has antigenic properties e.g., would have the ability to bind to antibodies or raise immune responses.

Art Unit: 1618

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Chicz discloses a peptide bound to HLA-dR1 derived from MHC-related molecules.

Rothbard et al teaches a degenerate binding of immunogenic peptides to HLA-DR proteins.

Jackson et al discloses a synthetic peptide to HA.

Tang et al describes synthetic peptide of HA.

Busch et al discloses the effect of natural polymorphism at residue 86 of the HLA-DR chain on peptide binding.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1627.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. Wessendorf whose telephone number is (703) 3967. The examiner can normally be reached on Mon. to Fri. from 8 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald E. Adams, Ph.D., can be reached on (703) 308-0570. The fax phone number for this Group is (703) 308-7924.

Art Unit: 1618

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Tdw

1/31/00

T. Wenzelby

Patient Examiner